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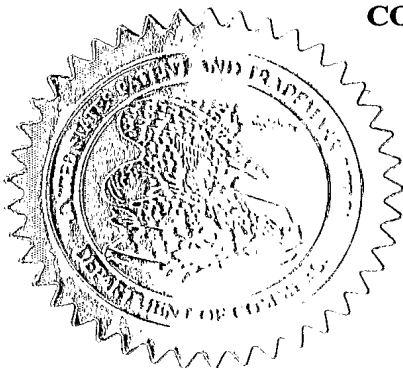
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PROVISIONAL APPLICATION FOR PATENT COVER SHEET


This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No.

INVENTOR(S)						
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<input type="checkbox"/> Additional inventors are being named on the <u>0</u> separately numbered sheets attached hereto						
TITLE OF THE INVENTION (280 characters max)						
METHOD AND APPARATUS FOR DETECTION OF RESPIRATORY DISORDER BY IMPLANTABLE DEVICE						
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ENCLOSED APPLICATION PARTS (check all that apply)						
<input checked="" type="checkbox"/> Specification Number of Pages		3		<input type="checkbox"/> CD(s), Number		<input type="text"/>
<input checked="" type="checkbox"/> Drawing(s) Number of Sheets		1		<input checked="" type="checkbox"/> Other (specify)		return itemized postcard
<input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76						
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT						
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.						
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Respectfully submitted,

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2/20/2004

REGISTRATION NO.
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44,617

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METHOD AND APPARATUS FOR DETECTION AND TREATMENT OF RESPIRATORY DISORDER BY IMPLANTABLE DEVICE

This method detects a respiratory disorder by measuring transthoracic impedance changes via implanted electrodes. This uses relatively high frequency (eg 20Hz) electrical pulses (compared with respiration or heart rate) that have amplitude below the level needed to stimulate excitable tissue. The impedance is calculated by measuring current & voltage and calculating impedance via Ohm's Law. Impedance changes are correlated with thorax movements. Patterns of movement are detected and used to indicate a variety of respiratory disorders such as Obstructive Apnea, central apnea, cheyne-Stokes respiration.

Identification of a respiratory disorder in such a manner can be used to control or initiate treatment of the disorder by electrical stimulation or by adjustment of treatment pressure. Stimulation can be of respiratory efferent nerves such as the phrenic nerve to stimulate breathing, with or without upper airway stimulation. A second method is to stimulate afferent nerves, which serve as an input to central nervous system respiratory control in order to modulate the respiration. For example, it is known that CSR (Cheyne-Stokes respiration) is as a result of an unstable respiratory controller in the CNS (central nervous system). Electrical Stimulation of afferent nerves serves to stabilise the respiratory controller by stimulating respiration when it is suppressed and not stimulating during periods of sufficient respiration, or during periods of over breathing stimulate the afferent system in order to suppress respiration. For example, afferent nerves stimulated by cardiac pacing, or by stimulation of the upper airway, can serve to modulate the respiratory controller.

An example of a methodology as described is illustrated in Figure 1.

DETECTION OF RESPIRATORY PARAMETER AS INDICATOR OF HEART FAILURE SEVERITY

It is known that the duration of respiration and apnea periods during CSR is related to the severity of CHF as disclosed in pending United States Provisional Patent application 60/512,553 filed 17th October 2003, the disclosure of which is incorporated by cross reference. For example, a longer respiration plus apnea period is indicative of more severe CHF. In addition the relationship of these periods is indicative of CHF condition. Analysis of the respiration patterns derived from a measurement of transthoracic impedance, either using electrodes placed externally or internally on the

thorax, can be used for example, to detect such periods and also serve as an indicator of CHF condition.

The analysis of the respiration and reporting of cardiac dysfunction can be implemented either in an implantable device (e.g., a pacemaker) or an external monitor (e.g. holter monitor). Such devices may optionally be configured to be in communication with a flow generator type SDB treatment device or flow monitoring device known in the art.

A METHOD TO TREAT SDB USING RESPIRATION DETERMINED CARDIAC OVERDRIVE PACING.

It is known that pacing the heart at 15 beats per minute above the nominal rate can resolve OSA (ref Garrigue, 2002). However it is not desirable to permanently pace the heart at rates higher than necessary to maintain cardiac function.

Respiratory abnormalities are detected by analysis of respiratory patterns, measurement of transthoracic impedance, for example, as described previously. When apneas are detected either by detecting flow conditions in an automated SDB device and/or by transthoracic impedance monitoring with an automated impedance detector and controller, etc., the pacing rate is increased. If no further apneas are detected for a period (e.g. 20 minutes) the pacing rate is gradually reduced to the nominal value. If further apneas are detected, the pacing rate is increased.

METHOD FOR DETECTION AND DISCRIMINATION OF CENTRAL AND OBSTRUCTIVE APNEA IN IMPLANTABLE DEVICE

It is known that central apnea and obstructive apnea can be discriminated by measuring and comparing both respiratory airflow and thoracic movement.

A method for measuring air flow in an implantable device is by use of an acoustic transducer inside the device, such as a microphone, or from a transmitted signal from an external device in communication with the implantable device. Analysis of the frequency and amplitude of the sound can be used to deduce relative airflow. In addition, snoring, which is indicative of a partial obstruction of the upper airway can be detected. It is known that snoring is frequently a precursor of obstructive apnea.

A method for indicating thoracic movement is by measuring the electrical impedance between two or more implanted electrodes.

By a combination of methods for deducing airflow and thoracic movement, it is possible to discriminate between central and obstructive apnea in an implantable device. For example, if thoracic movements are detected without corresponding airflow, it is possible to deduce that there is obstructive apnea occurring. If there is no airflow and no thoracic movements for a specified period, it is possible to deduce that there is central apnea.

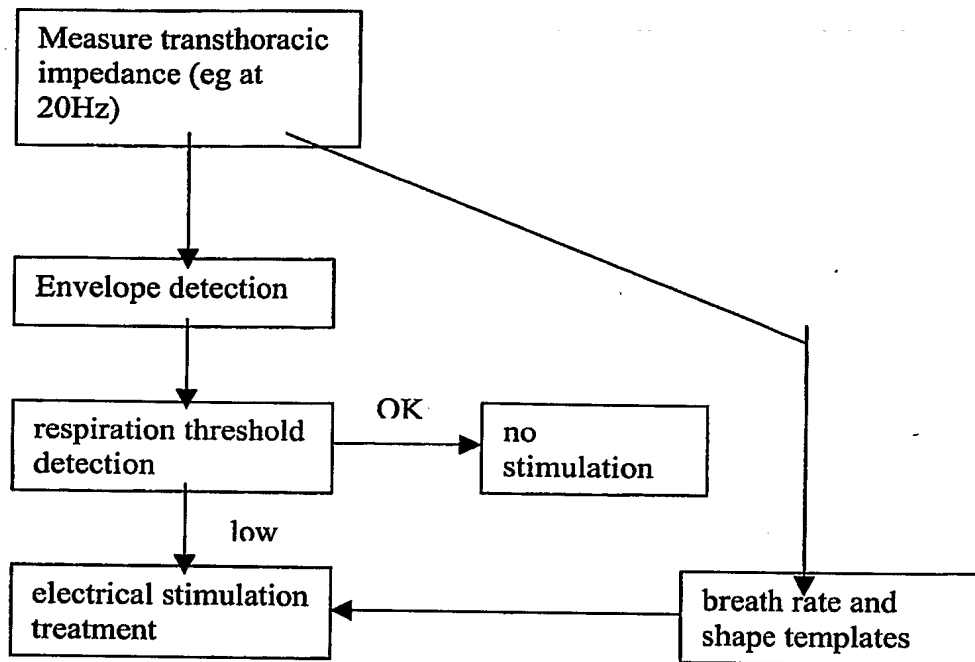


FIGURE 1